UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

CHERYL PALMA and JAMES PALMA, Plaintiffs, -against- JOHNSON & JOHNSON, ETHICON, INC., ETHICON, LLC, AMERICAN MEDICAL SYSTEMS, INC., DEFENDANT AMERICAN MEDICAL SYSTEMS, HOLDINGS INC., ENDO PHARMACEUTICALS, INC., ENDO PHARMACEUTICALS HOLDINGS, INC., and ENDO HEALTH SOLUTIONS INC., Defendants.	CASE NO. 2:22-cv-1702 COMPLAINT AND JURY DEMAND

CIVIL ACTION COMPLAINT

Plaintiff CHERYL PALMA and JAMES PALMA (collectively, "Plaintiffs" or simply "Plaintiff" when referring to only Ms. Palma), by and through their counsel, LIEFF CABRASER HEIMANN & BERNSTEIN, LLP, bring this Complaint against two groups of defendants: 1) Defendants Johnson & Johnson, Ethicon, Inc., and Ethicon, LLC (collectively, "Ethicon Defendants"), and 2) Defendants American Medical Systems, Inc., Defendant American Medical Systems, Holdings Inc., Endo Pharmaceuticals, Inc., Endo Pharmaceuticals Holdings, Inc., and Endo Health Solutions Inc. (collectively, "AMS Defendants"). (Ethicon Defendants and AMS Defendants, when referenced together, collectively "Defendants").

Plaintiffs bring this Complaint against Defendants for injuries suffered as a result of a two defective pelvic mesh products, one manufactured and marketed by each defendant group.

Plaintiff was implanted with a pelvic mesh marketed as the Gynecare-TVT designed, developed, manufactured, marketed and sold by the Ethicon Defendants. Gynecare-TVT caused Plaintiff injuries as outlined herein.

Plaintiff was also implanted with pelvic meshes marketed as the Elevate Anterior/Apical System and Apical/Posterior System designed, developed, manufactured, marketed and sold by the AMS Defendants. These devices caused Plaintiff injuries as outlined herein.

In support, Plaintiffs state and aver as follows:

I. PARTIES

A. Plaintiff

1. Plaintiffs CHERYL PALMA and JAMES PALMA are and were, at all relevant times, a resident and citizen of the State of New York, in Nassau County.

2. On or about March 5, 2013, Plaintiff was implanted with the AMS Defendants' pelvic mesh products named Elevate Anterior/Apical System and Apical/Posterior Systems; during the same procedure, on the same date, Plaintiff was implanted with Ethicon Defendants' Gynecare-TVT pelvic mesh product. Collectively, the pelvic devices implanted in plaintiff are referred to as "Pelvic Mesh Products" or simply "Products".

3. Plaintiff was implanted with these products to treat, uterovaginal prolapse, cystocele, rectocele, and enterocele.

4. In April 2019, Plaintiff developed vaginal odor and discharge, which was persistent despite several rounds of antibiotic treatment.

5. Later, Plaintiff discovered that the antibiotic treatments were ineffective because she had a MRSA infection, caused by extrusions and erosions of the aforementioned pelvic mesh products that were implanted inside of her.

6. As outlined in further detail herein, Defendants' Products are defective because of their propensity to creep, contract, retract, and shrink inside the body. If not for these defects in the Defendants' Products implanted inside of Plaintiff, the MRSA infection would not have had "folds" and other deep formation areas that allowed for the MRSA infection to take hold. In short, the defects as outlined herein in Defendants' Products caused or exacerbated Plaintiff's MRSA infection.

7. On July 24, 2019, Plaintiff underwent a revision surgery to correct mesh extrusion with vaginal infection.

8. It was not until shortly before a July 24, 2019 revision surgery that Plaintiff discovered, or reasonably could have discovered, that the Defendants' pelvic mesh products had failed.

9. As outlined in further detail herein, Defendants' Products are also defective because of their propensity to cause extrusion and erosion, degrade, and fragment inside the body. If not for these defects in the Defendants' Products implanted inside of Plaintiff, the surgery to correct the mesh extrusion would not have been necessary.

10. In October 28, 2019, postoperative follow-up office visit revealed a yellowish/greenish discharge. A culture from the discharge showed that plaintiff suffered from a persistent MRSA infection. But for the failure of the Defendants' pelvic meshes, Plaintiff would not have suffered this infection nor the aforementioned extrusion and erosion.

11. Plaintiff's suffering, therefore, continued. Plaintiff had to undergo a second procedure on December 10, 2019, to remove all of the remaining MRSA-infected mesh. All of the aforementioned pelvic mesh products were carefully removed through an exploratory laparotomy lysis of adhesions procedure.

12. Plaintiff lost one liter of blood during this procedure, and was therefore extremely fatigued. Her recovery period, at minimum lasted 7 weeks' time.

13. As outlined in further detail herein, Defendants' Products are also defective because of their propensity to cause chronic inflammation and infection and to adhere to surrounding organs. If not for these defects in the Defendants' Products implanted inside of Plaintiff, the second surgery, to remove all pelvic mesh pieces and to clear out the remaining MRSA infection, would not have been necessary.

B. Defendants

1. Ethicon Defendants

14. Defendant, Johnson & Johnson ("J&J") is a corporation, and according to its website, the world's largest and most diverse medical device and diagnostics company, with its worldwide headquarters located at One Johnson & Johnson Plaza, New Brunswick, New Jersey. Johnson & Johnson organizes its subsidiary businesses into individual Business Units to coordinate the development, manufacture, testing, marketing promotion, training, distribution and sale of its' pelvic floor repair products. Within J&J there are three sectors, medical devices and diagnostics, pharmaceutical, and consumer. Within the medical devices and diagnostic sector are "Business Units" including the "Ethicon Franchise." The Ethicon Franchise was charged by J&J with the design, development, promotion, marketing, testing, training, distribution and sale of the pelvic floor repair products at issue in this case. The Company Group Chairman and Worldwide Franchise Chairman for the Ethicon Franchise, Gary Pruden, is employed by J&J. The companies which comprise the Ethicon Franchise are thus controlled by J&J and include, but are not limited to, Ethicon Inc., Ethicon LLC, Ethicon LTD.

15. Defendant, Ethicon, Inc., is a wholly owned subsidiary of Defendant Johnson & Johnson located in Somerville, New Jersey.

16. Defendant, Ethicon, LLC, is a wholly owned subsidiary of Johnson & Johnson Medical, Inc., located in San Lorenzo, Puerto Rico. Ethicon LLC was charged by J&J with the manufacture of Ethicon Inc.'s pelvic floor repair products.

17. At all times material to this action, the Ethicon Defendants have designed, patented, manufactured, labeled, marketed, and sold and distributed a line of pelvic mesh products. These products were designed primarily for the purposes of treating stress urinary incontinence and pelvic organ prolapse. These products share common design elements and common defects. Moreover, each of these products was cleared for sale in the U.S. after the Defendants made assertions to the Food and Drug Administration of "Substantial Equivalence" under Section 510(k) of the Food, Drug and Cosmetic Act; this clearance process does not require the applicant to prove safety or efficacy.

18. At all times relevant herein, the Ethicon Defendants were engaged in the business of placing medical devices into the stream of commerce by designing, manufacturing, testing, training, marketing, promoting, packaging, labeling, and/or selling such devices, including the Gynecare TVT implanted in Plaintiff. Defendants manufacture, market, advertise, promote and sell pelvic mesh products, including Gynecare TVT implanted in Plaintiff, worldwide. As a result of the coordinated activities of the Ethicon Defendants named above, Plaintiff was implanted with a defective pelvic floor repair product.

19. The Ethicon Defendants had a legal duty to insure the safety and effectiveness of their pelvic mesh products by conducting adequate and well controlled studies on their products prior to marketing. Ethicon Defendants deliberately chose to manipulate the only studies that were conducted on their products and by so doing provided doctors and patients with false and misleading information about the safety and effectiveness of their pelvic mesh products.

Furthermore, the Ethicon Defendants made a conscious decision to forego performing studies and creating registries that would have provided doctors and patients in the United States with accurate information regarding the lack of proof of the safety and effectiveness of their pelvic mesh products.

20. All acts and omissions of each Ethicon Defendant as described herein were accomplished by its agents, servants, employees, and/or owners, acting in the course and scope of their respective agencies, services, employments, and/or ownership.

2. AMS Defendants

21. American Medical Systems, Inc. ("AMS") is a wholly owned subsidiary of defendant American Medical Systems Holdings Inc., Defendant AMS is a wholly owned subsidiary of defendant Endo Pharmaceuticals, Inc., Endo Pharmaceuticals Holdings Inc. and Endo Health Solutions Inc. and is a Delaware corporation and may be served pursuant to 10 Del. C. § 3111 by serving its registered agent, Corporation Trust Company, at 1209 N. Orange Street, Wilmington, Delaware 19801.

22. Defendant American Medical Systems, Holdings Inc., ("AMS HOLDINGS") is a Delaware corporation and may be served pursuant to 10 Del. C. § 3111 by serving its registered agent, Corporation Trust Company, at 1209 N. Orange Street, Wilmington, Delaware 19801 and is the parent of wholly-owned subsidiary AMS.

23. Defendant Endo Pharmaceuticals, Inc. (ENDO) is a Pennsylvania corporation, with its principal place of business at 100 Endo Boulevard, Chadds Ford, Pennsylvania. 19317.

24. Defendant Endo Pharmaceuticals Holdings, Inc. (ENDO HOLDINGS) was a Delaware corporation with its principal place of business at 100 Endo Boulevard, Chadds Ford, Pennsylvania 19317. ENDO HOLDINGS was the parent of wholly-owned subsidiary, ENDO. On May 23, 2012, ENDO HOLDINGS changed its name to Endo Health Solutions, Inc.

25. Defendant Endo Health Solutions Inc. (ENDO HEALTH SOLUTIONS) is a Delaware corporation with its principal place of business at 100 Endo Boulevard, Chadds Ford, Pennsylvania 19317. and is the parent of AMS and AMS HOLDINGS.

26. Defendant ENDO HEALTH SOLUTIONS has aggregated four operating businesses into one enterprise including AMS and AMS HOLDINGS.

27. At all relevant times, defendant ENDO merged with AMS and as part of that acquisition, purchased and assumed all liability relating to legal claims arising from the implantation of defective synthetic pelvic mesh systems.

28. At all times material to this action, the AMS Defendants have designed, patented, manufactured, labeled, marketed, and sold and distributed a line of pelvic mesh products. These products were designed primarily for the purposes of treating stress urinary incontinence and pelvic organ prolapse. These products share common design elements and common defects. Moreover, each of these products was cleared for sale in the U.S. after the Defendants made assertions to the Food and Drug Administration of "Substantial Equivalence" under Section 510(k) of the Food, Drug and Cosmetic Act; this clearance process does not require the applicant to prove safety or efficacy.

29. At all times relevant herein, the AMS Defendants were engaged in the business of placing medical devices into the stream of commerce by designing, manufacturing, testing, training, marketing, promoting, packaging, labeling, and/or selling such devices, including the Elevate Anterior/Apical System and Apical/Posterior System implanted in Plaintiff. AMS Defendants manufacture, market, advertise, promote and sell pelvic mesh products, including the Elevate Anterior/Apical System and Apical/Posterior System implanted in Plaintiff, worldwide.

As a result of the coordinated activities of the AMS Defendants named above, Plaintiff was implanted with a defective pelvic floor repair product.

30. The AMS Defendants had a legal duty to insure the safety and effectiveness of their pelvic mesh products by conducting adequate and well controlled studies on their products prior to marketing. Defendants deliberately chose to manipulate the only studies that were conducted on their products and by so doing provided doctors and patients with false and misleading information about the safety and effectiveness of their pelvic mesh products. Furthermore, the AMS Defendants made a conscious decision to forego performing studies and creating registries that would have provided doctors and patients in the United States with accurate information regarding the lack of proof of the safety and effectiveness of their pelvic mesh products.

31. All acts and omissions of each AMS Defendant as described herein were accomplished by its agents, servants, employees, and/or owners, acting in the course and scope of their respective agencies, services, employments, and/or ownership.

II. JURISDICTION AND VENUE

32. Damages sought in this matter are in excess of $75,000.00. Subject matter jurisdiction is proper pursuant to 28 U.S.C. §1332.

33. This Court has subject matter jurisdiction over the parties pursuant to 28 U.S.C. §1332(a) because the parties are citizens of different states and the amount in controversy exceeds $75,000.00, exclusive of interest and costs.

34. Venue is proper in the Eastern District of New York pursuant to 28 U.S.C. §1391 because a substantial part of the events giving rise to this claim occurred in this District.

35. Defendants conducted substantial business in this District, distributed their respective pelvic mesh products in this District, received substantial compensation and profits

from sales of pelvic mesh products in this District, and made material omissions and misrepresentations and breaches of warranties in this District so as to subject them to *in personam* jurisdiction in this District.

36. Defendants conducted business in the State of New York through sales representatives; and, because Defendants were engaged in testing, developing, manufacturing, labeling, marketing, distributing, promotion and selling, either directly or indirectly, and/or through third parties or related entities, pelvic mesh products, including the product that was implanted in Plaintiff, there exists a sufficient nexus between Defendants' forum contacts and the Plaintiff's claims to justify assertion of jurisdiction in New York.

37. All acts and omissions of Defendants, as described herein, were done by its agents, servants, employees, directors, managers and/or owners acting in the course and scope of their respective agencies, services, employment, and/or ownership.

III. FACTUAL BACKGROUND

38. Surgical mesh products have been used to repair abdominal hernias since the 1950s. In the 1970s, gynecologists began using surgical mesh products designed for hernia repair for abdominal repair to surgically repair prolapsed organs. In the 1990s, gynecologists began using this surgical mesh for the surgical treatment of pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). Manufacturers, including Defendants, began to modify the mesh used in hernia repair to be used as products specifically intended to correct POP an SUI. Today, defendants sell pelvic mesh "kits" which can include not only the surgical mesh, but also tissue fixation anchors and insertion tools. The Products manufactured by Defendants are considered Class II medical devices.

39. Defendants' Pelvic Mesh Products are targeted for women who suffer from pelvic organ prolapse and stress urinary incontinence as a result of the weakening or damage caused to

the walls of the vagina. These products are specifically promoted to physicians and patients as an innovative, minimally invasive procedure with minimal local tissue reactions, minimal tissue trauma and minimal pain while correcting vaginal prolapse, stress urinary incontinence, pelvic organ prolapse and/or rectocele.

40. Moreover, these Pelvic Mesh Products contain polypropylene mesh. Despite claims that this material is inert, the scientific evidence shows that this mesh material is biologically incompatible with human tissue and promotes an immune response in a large subset of the population receiving Defendants' Pelvic Mesh Products. This immune response promotes degradation of the polypropylene mesh, as well as the pelvic tissue, and can contribute to the formation of severe adverse reactions to the mesh.

41. At various times, Defendants sought and obtained Food and Drug Administration ("FDA") clearance to market the Pelvic Mesh Products under Section 510(k) of the Medical Device Amendment. Section 510(k) allows marketing of medical devices if the device is deemed substantially equivalent to other legally marketed predicate devices marketed prior to May 28, 1976. This clearance process did not require Defendants to prove the safety or efficacy of the Pelvic Mesh Products and, thus, a formal review of the safety and efficacy of the Pelvic Mesh Products was never conducted with regard to the Products. In the case of the Prolift product, Defendants marketed and sold the product for human implantation for over two years without the necessary clearance under Section 510(k)

42. Defendants' Pelvic Mesh Products have been and continue to be marketed to the medical community and directly to patients as safe, effective, reliable, medical devices; implanted by safe and effective, minimally invasive surgical techniques for the treatment of medical conditions, primarily vaginal vault prolapse, stress urinary incontinence, pelvic organ

prolapse and/or rectocele, and as safer and more effective as compared to the traditional products and procedures for treatment, and other competing Pelvic Mesh Products.

43. The Defendants have marketed and sold the Pelvic Mesh Products to the medical community at large and directly to patients through carefully planned, multifaceted marketing campaigns and strategies. These campaigns and strategies include, but are not limited to, aggressive marketing to health care providers at medical conferences, hospitals, private offices, and include the provision of valuable cash and non-cash benefits to health care providers. Defendants also utilized documents, patient brochures, and websites, offering exaggerated and misleading expectations as to the safety and utility of the Pelvic Mesh Products. Defendants' further engaged in direct-to-consumer marketing specifically designed to drive consumers to seek out these products for implantation into their bodies.

44. At all times relevant to this action, Defendants intentionally, recklessly and/or negligently concealed, suppressed, omitted, and misrepresented the risks, dangers, defects, and disadvantages of the Pelvic Mesh Products and advertised, promoted, marketed, sold and distributed the Pelvic Mesh Products as a safe medical device when, in fact, Defendants knew that the Pelvic Mesh Products were not safe for their intended purposes and that the Pelvic Mesh Products would cause, and did cause, serious medical problems, and in some patients, catastrophic and permanent injuries.

45. For example, Defendants described in its Patient Brochures, Instructions for Use, and other marketing materials, that the known complications for its Pelvic Mesh Products were consistent with any surgical procedure of an implantable medical device and described such occurrences as "rare" and "small" when in fact Defendants knew or should have known that the complications were not "rare nor small" but common, permanent, and debilitating.

46. Defendants' Pelvic Mesh Products contain monofilament polypropylene mesh and/or collagen. Despite claims that polypropylene is inert, the scientific evidence shows that this material as implanted in the Plaintiff is biologically incompatible with human tissue and promotes a negative immune response in a large subset of the population implanted with Defendants' Pelvic Mesh Products. This negative response promotes inflammation of the pelvic tissue and can contribute to the formation of severe adverse reactions to the mesh. Furthermore, Defendants' collagen products cause hyper-inflammatory responses leading to problems including chronic pain and fibrotic reaction. Defendants' collagen products disintegrate after implantation in the female pelvis. The collagen products cause adverse tissue reactions, and are causally related to infection, as the collagen is a foreign material derived from animal tissue. Animal collagen is harsh upon the female pelvic tissue. It hardens in the body. When mesh is inserted in the female body according to the manufacturers' instructions, it creates a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities.

47. On October 20, 2008, the Food and Drug Administration ("FDA") issued a Public Health Notification that described over 1,000 reports of complications (otherwise known as "adverse events") that had been reported over a three-year period relating to pelvic mesh products. Although the FDA notice did not identify the transvaginal mesh manufacturers by name, a review of the FDA's MAUDE database indicates that the Defendant is one of the manufacturers of the products that are the subject of the notification. In 2008, the FDA described the complications associated with pelvic mesh products as "**rare**."

48. On July 13, 2011, the FDA issued a Safety Communication wherein the FDA stated that "serious complications associated with surgical mesh for transvaginal repair of POP are **not rare**" (emphasis in the original).

49. The FDA Safety Communication also stated, "*Mesh contraction* (shrinkage) is a *previously unidentified risk* of transvaginal POP repair with mesh that has been reported in the published scientific literature and in adverse event reports to the FDA . . . Reports in the literature associate mesh contraction with vaginal shortening, vaginal tightening and vaginal pain." (emphasis in original).

50. The FDA Safety Communication further indicated that the benefits of using transvaginal mesh products instead of other feasible alternatives did not outweigh the associated risks.

51. Specifically, the FDA Safety Communication stated: "it is not clear that transvaginal POP repair with mesh is more effective than traditional non-mesh repair in all patients with POP and it may expose patients to greater risk."

52. Contemporaneously with the Safety Communication, the FDA released a publication titled "Urogynecologic Surgical Mesh: Update on the Safety and Effectiveness of Transvaginal Placement for Pelvic Organ Prolapse" (the "White Paper"). In the White Paper, the FDA noted that the published, peer-reviewed literature demonstrates that "[p]atients who undergo POP repair with mesh are subject to mesh-related complications that are not experienced by patients who undergo traditional surgery without mesh."

53. The FDA summarized its findings from its review of the adverse event reports and applicable literature stating that it "has NOT seen conclusive evidence that using transvaginally placed mesh in POP repair improves clinical outcomes any more than traditional POP repair that does not use mesh, and it may expose patients to greater risk." (Emphasis in original).

54. The FDA White Paper further stated that "these products are associated with serious adverse events . . . Compounding the concerns regarding adverse events are performance data that fail to demonstrate improved clinical benefit over traditional non-mesh repair."

55. In its White Paper, the FDA advises doctors to, *inter alia*, "[r]ecognize that in most cases, POP can be treated successfully without mesh thus avoiding the risk of mesh-related complications."

56. The FDA concludes its White Paper by stating that it "has identified serious safety and effectiveness concerns over the use of surgical mesh for the transvaginal repair of pelvic organ prolapse."

57. At the time Defendants began marketing each of its Pelvic Mesh Products, Defendants were aware that its Pelvic Mesh Products were associated with each and every one of the adverse events communicated by the FDA in its July 13, 2011 Safety Communication,

58. The information contained in the FDA's Public Health Notification of October 2008 and the FDA Safety Communication of July 13, 2011 was known or knowable to Defendants and was not disclosed in oral or written communications, direct to consumer advertising in the form of patient brochures, instructions of use or labeling.

59. In a December 2011 Joint Committee Opinion, the American College of Obstetricians and Gynecologists ("ACOG") and the American Urogynecologic Society ("AUGS") also identified physical and mechanical changes to the mesh inside the body as a serious complication associated with vaginal mesh, stating:

> There are increasing reports of vaginal pain associated with changes that can occur with mesh (contraction, retraction, or shrinkage) that result in taut sections of mesh . . . Some of these women will require surgical intervention to correct the condition, and some of the pain appears to be intractable.

60. The ACOG/AUGS Joint Committee Opinion also recommended, among other things, that "[p]elvic organ prolapse vaginal mesh repair should be reserved for high-risk individuals in whom the benefit of mesh placement may justify the risk."

61. The injuries of the female Plaintiff as will be more fully set forth in the Plaintiff's Fact Sheet to be served in this civil action are reported in the FDA Safety Communication and in the ACOG/AUGS Joint Committee Opinion.

62. Defendants knew or should have known about the Products' risks and complications identified in the FDA Safety Communication and the ACOG/AUGS Joint Committee Opinion.

63. Defendants knew or should have known that the Products unreasonably exposed patients to the risk of serious harm while conferring no benefit over available feasible alternatives that do not involve the same risks.

64. The scientific evidence shows that the material from which Defendants' Products are made is biologically incompatible with human tissue and promotes a negative immune response in a large subset of the population implanted with the Products, including Plaintiff.

65. This negative response promotes inflammation of the pelvic tissue and contributes to the formation of severe adverse reactions to the mesh, such as those experienced Plaintiff.

66. The FDA defines both "degradation" and "fragmentation" as "device problems" to which the FDA assigns a specific "device problem code." "Material fragmentation" is defined as an "[i]ssue associated with small pieces of the device breaking off unexpectedly" and "degraded" as an "[i]ssue associated with a deleterious change in the chemical structure, physical properties, or appearance in the materials that are used in device construction." The Products were unreasonably susceptible to degradation and fragmentation inside the body.

67. The Products were unreasonably susceptible to shrinkage and contraction inside the body.

68. The Products were unreasonably susceptible to "creep" or the gradual elongation and deformation when subject to prolonged tension inside the body.

69. The Products have been and continue to be marketed to the medical community and to patients as safe, effective, reliable, medical devices, implanted by safe and effective, minimally invasive surgical techniques, and as safer and more effective as compared to available feasible alternative treatments of pelvic organ prolapse and stress urinary incontinence, and other competing products.

70. Defendants omitted the risks, dangers, defects, and disadvantages of the Products, and advertised, promoted, marketed, sold and distributed the Products as safe medical devices when Defendants knew or should have known that the Products were not safe for their intended purposes, and that the Products would cause, and did cause, serious medical problems, and in some patients, including Plaintiff, catastrophic injuries.

71. Contrary to Defendants' representations and marketing to the medical community and to the patients themselves, the Products have high rates of failure, injury, and complications, fail to perform as intended, require frequent and often debilitating re-operations, and have caused severe and irreversible injuries, conditions, and damage to a significant number of women, including Plaintiff, making them defective under the law.

72. The specific nature of the Products' defects includes, but is not limited to, the following:

a. the use of polypropylene and collagen material in the Products and the immune reactions that result from such material, causing adverse reactions and injuries;

b. the design of the Products to be inserted transvaginally, into and through an area of the body with high levels of bacteria that can adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

c. biomechanical issues with the design of the Products, including, but not limited to, the propensity of the Products to contract or shrink inside the body, that in turn cause surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury;

d. the use and design of arms and anchors in the Products, which, when placed in the women, are likely to pass through contaminated spaces and that can injure major nerve routes in the pelvic region;

e. the propensity of the Products for "creep," or to gradually elongate and deform when subject to prolonged tension inside the body;

f. the inelasticity of the Products, causing them to be improperly mated to the delicate and sensitive areas of the vagina and pelvis where they are implanted, and causing pain upon normal daily activities that involve movement in the pelvic region (e.g., intercourse, defecation, walking); and

g. the propensity of the Products for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time;

h. the hyper-inflammatory responses to collagen leading to problems including chronic pain and fibrotic reaction;

i. the propensity of the collagen products to disintegrate after implantation in the female pelvis, causing pain and other adverse reactions;

j. the adverse tissue reactions caused by the collagen products, which are causally related to infection, as the collagen is a foreign organic material from animals;

k. the harshness of animal collagen upon the female pelvic tissue, and the hardening of the product in the body;

l. the creation of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanted according to the manufacturers' instructions;

m. the procedure itself, which is part of Defendants' Pelvic Mesh Products, requires the physician to insert the device "blindly" resulting in nerve damage and damage to other internal organs;

n. the design of trocars, as devices which as part of Defendants' Pelvic Mesh Products and which are used to insert the Pelvic Mesh Products into the vagina, are defective because the device requires tissue penetration in nerve rich environments which results frequently in the destruction of nerve endings causing pain and other injuries.

73. The Products are also defective due to Defendants' failure to adequately warn or instruct Plaintiff and/or her health care providers of subjects including, but not limited to, the following:

a. the Products' propensities to contract, retract, and/or shrink inside the body;

b. the Products' propensities for degradation, fragmentation and/or creep;

c. the Products' inelasticity preventing proper mating with the pelvic floor and vaginal region;

d. the rate and manner of mesh erosion or extrusion;

e. the risk of chronic inflammation resulting from the Products;

f. the risk of chronic infections resulting from the Products;

g. the risk of permanent vaginal or pelvic scarring as a result of the Products;

h. the risk of permanent vaginal shortening resulting from the Products;

i. the risk of recurrent, intractable pelvic pain and other pain resulting from the Products;

j. the need for corrective or revision surgery to adjust or remove the Products;

k. the severity of complications that could arise as a result of implantation of the Products;

l. the hazards associated with the Products;

m. the Products' defects described herein;

n. treatment of pelvic organ prolapse and stress urinary incontinence with the Products is no more effective than feasible available alternatives;

o. treatment of pelvic organ prolapse and stress urinary incontinence with the Products exposes patients to greater risk than feasible available alternatives;

p. treatment of pelvic organ prolapse and stress urinary incontinence with the Products makes future surgical repair more difficult than feasible available alternatives;

q. use of the Products puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

r. removal of the Products due to complications may involve multiple surgeries and may significantly impair the patient's quality of life; and

s. complete removal of the Products may not be possible and may not result in complete resolution of the complications, including pain.

74. Defendants have underreported information about the propensity of the Products to fail and cause injury and complications, and have made unfounded representations regarding the efficacy and safety of the Products through various means and media. Defendants have also underreported information about the injuries caused by the use of the implantation kits and surgical technique instructions that accompany their pelvic meshes.

75. Defendants failed to perform proper and adequate testing and research in order to determine and evaluate the risks and benefits of the Products.

76. Defendants failed to design and establish a safe, effective procedure for removal of the Products, or to determine if a safe, effective procedure for removal of the Products exists.

77. Feasible and suitable alternatives to the Products have existed at all times relevant that do not present the same frequency or severity of risks as do the Products.

78. The Products were at all times utilized and implanted in a manner foreseeable to Defendants, as Defendants generated the instructions for use, created the procedures for implanting the devices, provided the surgical kits for implantation, and provided training for the implanting physician.

79. Defendants provided incomplete and insufficient training and information to physicians regarding the use of the Products and the aftercare of patients implanted with the Products.

80. The Product or products implanted in Plaintiff were in the same or substantially similar condition as they were when they left Defendants' possession, and in the condition directed by and expected by Defendants.

81. The injuries, conditions, and complications suffered by numerous women around the world who have been implanted with the Products include, but are not limited to, erosion, mesh contraction, infection, fistula, inflammation, scar tissue, organ perforation, dyspareunia (pain during sexual intercourse), blood loss, neuropathic and other acute and chronic nerve damage and pain, pudendal nerve damage, pelvic floor damage, chronic pelvic pain and other debilitating complications.

82. In many cases, including Plaintiff, the women have been forced to undergo extensive medical treatment, including, but not limited to, operations to locate and remove mesh, operations to attempt to repair pelvic organs, tissue, and nerve damage, the use of pain control and other medications, injections into various areas of the pelvis, spine, and the vagina, and operations to remove portions of the female genitalia.

83. The medical and scientific literature studying the effects of Defendants' mesh products, like that of the products implanted in Plaintiff, has examined each of these injuries, conditions, and complications, and has reported that they are causally related to the Products.

84. Removal of contracted, eroded and/or infected mesh can require multiple surgical interventions for removal of mesh and results in scarring on fragile compromised pelvic tissue and muscles.

85. At all relevant times herein, Defendants continued to promote the Products as safe and effective even when no clinical trials had been done supporting long- or short-term efficacy.

86. In doing so, Defendants failed to disclose the known risks and failed to warn of known or scientifically knowable dangers and risks associated with the Products.

87. At all relevant times herein, Defendants failed to provide sufficient warnings and instructions that would have put Plaintiff and the general public on notice of the dangers and adverse effects caused by implantation of the Products.

88. The Products as designed, manufactured, distributed, sold and/or supplied by Defendants were defective as marketed due to inadequate warnings, instructions, labeling and/or inadequate testing in the presence of Defendants' knowledge of lack of safety.

89. As a result of having the Products implanted in her, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and other damages.

90. Defendants had a duty to individuals, including Plaintiff, to use reasonable care in designing, manufacturing, marketing, labeling, packaging and selling the Products.

91. Defendants were negligent in failing to use reasonable care as described herein in designing, manufacturing, marketing, labeling, packaging and selling the Products. Defendants breached their aforementioned duty by:

a. Failing to design the Products so as to avoid an unreasonable risk of harm to women in whom the Products were implanted, including Plaintiff;

b. Failing to manufacture the Products so as to avoid an unreasonable risk of harm to women in whom the Products were implanted, including Plaintiff;

c. Failing to use reasonable care in the testing of the Products so as to avoid an unreasonable risk of harm to women in whom the Products were implanted, including Plaintiff;

d. Failing to use reasonable care in inspecting the Products so as to avoid an unreasonable risk of harm to women in whom the Products were implanted, including Plaintiff;

e. Otherwise negligently or carelessly designing, manufacturing, marketing, labeling, packaging and/or selling the Products.

92. The reasons that Defendants' negligence caused the Products to be unreasonably dangerous and defective include, but are not limited to:

a. the use of polypropylene material and/or collagen material in the Products and the immune reaction that results from such material, causing adverse reactions and injuries;

b. the design of the Products to be inserted into and through an area of the body with high levels of bacteria that adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

c. biomechanical issues with the design of the Products, including, but not limited to, the propensity of the Products to contract or shrink inside the body, that in turn cause surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury;

d. the use and design of arms and anchors in the Products, which, when placed in the women, are likely to pass through contaminated spaces and injure major nerve routes in the pelvic region;

e. the propensity of the Products for "creep," or to gradually elongate and deform when subject to prolonged tension inside the body;

f. the inelasticity of the Products, causing them to be improperly mated to the delicate and sensitive areas of the pelvis where they are implanted, and causing pain upon normal daily activities that involve movement in the pelvis (e.g., intercourse, defecation); and

g. the propensity of the Products for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time;

h. the hyper-inflammatory responses to collagen leading to problems including chronic pain and fibrotic reaction;

i. the propensity of the collagen products to disintegrate after implantation in the female pelvis, causing pain and other adverse reactions;

j. the adverse tissue reactions caused by the collagen products, which are causally related to infection, as the collagen is a foreign organic material from animals;

k. the harshness of animal collagen upon the female pelvic tissue, and the hardening of the product in the body;

l. the creation of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanting according to the manufacturers' instructions.

93. Defendant also negligently failed to warn or instruct Plaintiff and/or her health care providers of subjects including, but not limited to, the following:

a. the Products' propensities to contract, retract, and/or shrink inside the body;

b. the Products' propensities for degradation, fragmentation and/or creep;

c. the Products' inelasticity preventing proper mating with the pelvic floor and vaginal region;

d. the rate and manner of mesh erosion or extrusion;

e. the risk of chronic inflammation resulting from the Products;

f. the risk of chronic infections resulting from the Products;

g. the risk of permanent vaginal or pelvic scarring as a result of the Products;

h. the risk of recurrent, intractable pelvic pain and other pain resulting from the Products;

i. the need for corrective or revision surgery to adjust or remove the Products;

j. the severity of complications that could arise as a result of implantation of the Products;

k. the hazards associated with the Products;

l. the Products' defects described herein;

m. treatment of pelvic organ prolapse and stress urinary incontinence with the Products is no more effective than feasible available alternatives;

n. treatment of pelvic organ prolapse and stress urinary incontinence with the Products exposes patients to greater risk than feasible available alternatives;

o. treatment of pelvic organ prolapse and stress urinary incontinence with the Products makes future surgical repair more difficult than feasible available alternatives;

p. use of the Products puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

q. removal of the Products due to complications may involve multiple surgeries and may significantly impair the patient's quality of life; and

r. complete removal of the Products may not be possible and may not result in complete resolution of the complications, including pain.

94. As a direct and proximate result of Defendants' negligence, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT I
STRICT LIABILITY – DESIGN DEFECT

95. Plaintiffs incorporate by reference all prior and subsequent paragraphs of this Complaint as if fully set forth herein and further allege as follows.

96. The Products implanted in Plaintiff were not reasonably safe for their intended uses and were defective as described herein with respect to their design. As previously stated, the Products' design defects include, but are not limited to:

a. the use of polypropylene material and/or collagen material in the Products and the immune reaction that results from such material, causing adverse reactions and injuries;

b. the design of the Products to be inserted into and through an area of the body with high levels of bacteria that adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

c. biomechanical issues with the design of the Products, including, but not limited to, the propensity of the Products to contract or shrink inside the body, that in turn cause surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury;

d. the use and design of arms and anchors in the Products, which, when placed in the women, are likely to pass through contaminated spaces and injure major nerve routes in the pelvic region;

e. the propensity of the Products for "creep," or to gradually elongate and deform when subject to prolonged tension inside the body;

f. the inelasticity of the Products, causing them to be improperly mated to the delicate and sensitive areas of the pelvis where they are implanted, and causing pain upon normal daily activities that involve movement in the pelvis (e.g., intercourse, defecation); and

g. the propensity of the Products for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time;

h. the hyper-inflammatory responses to collagen leading to problems including chronic pain and fibrotic reaction;

i. the propensity of the collagen products to disintegrate after implantation in the female pelvis, causing pain and other adverse reactions;

j. the adverse tissue reactions caused by the collagen products, which are causally related to infection, as the collagen is a foreign organic material from animals;

k. the harshness of animal collagen upon the female pelvic tissue, and the hardening of the product in the body;

l. the creation of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanting according to the manufacturers' instructions.

97. As a direct and proximate result of the Products' aforementioned defects as described herein, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo future medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages.

98. Defendants are strictly liable to Plaintiff for designing, manufacturing, marketing, labeling, packaging and selling a defective products.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT II
STRICT LIABILITY – FAILURE TO WARN

99. Plaintiffs incorporate by reference all prior and subsequent paragraphs of this Complaint as if fully set forth herein and further allege as follows.

100. The Products implanted in Plaintiff were not reasonably safe for their intended uses and were defective as described herein as a matter of law due to their lack of appropriate and necessary warnings. Specifically, Defendants did not provide sufficient or adequate warnings regarding, among other subjects:

a. the Products' propensities to contract, retract, and/or shrink inside the body;

b. the Products' propensities for degradation, fragmentation, disintegration and/or creep;

c. the Products' inelasticity preventing proper mating with the pelvic floor and vaginal region;

d. the rate and manner of mesh erosion or extrusion;

e. the risk of chronic inflammation resulting from the Products;

f. the risk of chronic infections resulting from the Products;

g. the risk of permanent vaginal or pelvic scarring as a result of the Products;

h. the risk of recurrent, intractable pelvic pain and other pain resulting from the Products;

i. the need for corrective or revision surgery to adjust or remove the Products;

j. the severity of complications that could arise as a result of implantation of the Products;

k. the hazards associated with the Products;

l. the Products' defects described herein;

m. treatment of pelvic organ prolapse and stress urinary incontinence with the Products is no more effective than feasible available alternatives;

n. treatment of pelvic organ prolapse and stress urinary incontinence with the Products exposes patients to greater risk than feasible available alternatives;

o. treatment of pelvic organ prolapse and stress urinary incontinence with the Products makes future surgical repair more difficult than feasible available alternatives;

p. use of the Products puts the patient at greater risk of requiring additional surgery than feasible available alternatives;

q. removal of the Products due to complications may involve multiple surgeries and may significantly impair the patient's quality of life; and

r. complete removal of the Products may not be possible and may not result in complete resolution of the complications, including pain.

101. As a direct and proximate result of the Products' aforementioned defects as described herein, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

102. Defendant is strictly liable to Plaintiff for designing, manufacturing, marketing, labeling, packaging and selling a defective products.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT III
FRAUDULENT CONCEALMENT

103. Plaintiffs incorporate by reference all prior and subsequent paragraphs of this Complaint as if fully set forth herein and further allege as follows.

104. On October 20, 2008, the Food and Drug Administration ("FDA") issued a Public Health Notification that described over 1,000 reports of complications (otherwise known as "adverse events") that had been reported over a three year period relating to pelvic mesh products. Although the FDA notice did not identify the transvaginal mesh manufacturers by name, a review of the FDA's MAUDE database indicates that the Defendant is one of the

manufacturers of the products that are the subject of the notification. In 2008, the FDA described the complications associated with pelvic mesh products as "rare."

105. The FDA further stated that "specific characteristics of patients at increased risk for complications have not been determined." As a result, the FDA recommended, among other things, Doctors "[o]btain specialized training for each mesh placement technique, and be aware of its risks."

106. Despite the FDA's statement that complications caused by the mesh were "rare", the Defendants knew at all times material to these actions that complications were, in fact not rare. Furthermore, the Defendants knew at all relevant times that the FDA's focus on training and surgical technique of the implanting physicians was misguided.

107. At all times prior to the October 20, 2008 Public Health Notification to the present, it was known or knowable to Defendants that their pelvic mesh products caused large numbers of complications that were not rare. Moreover, it was known or knowable to Defendants that the surgical technique and training of implanting physicians was not the cause of the adverse events associated with these devices. It was known or knowable to Defendants that the safety and efficacy of its pelvic mesh products had not been proven with respect to, among other things, the product, its components, its performance and its method of insertion. It was known or knowable to Defendants that there was not evidence that its pelvic mesh products were safe and effective and, in fact the evidence that was known or knowable to Defendants was that its pelvic mesh products were not safe and effective. Defendant continued to represent that its pelvic mesh products were safe and effective.

108. Despite what was known or knowable to Defendants about the lack of safety and efficacy of its pelvic mesh products prior to 2008, Defendants failed to disclose this information to the plaintiffs, to their physicians or to the public at large.

109. Despite this knowledge, Defendants continued to market and sell their pelvic mesh products and procedures as being safe and efficacious with evidence to the contrary. Additionally, Defendants wrongfully and intentionally, through their physician training program, provided physicians with the comfort that they had sufficient training, consistent with the 2008 FDA PHN, to minimize or eliminate adverse effects resulting from the devices.

110. At all times mentioned herein, Defendants, and each of them, had the duty and obligation to disclose to Plaintiff and to her physicians, the true facts concerning the aforesaid products, that is, that said products were dangerous and defective, lacking efficacy for its purported use and lacking safety in normal use, and how likely it was to cause serious consequences to users including permanent and debilitating injuries. Defendant concealed these material facts prior to the time that plaintiffs were implanted with Defendants' pelvic mesh products.

111. Defendants were under a duty to Plaintiffs to disclose and warn of the defective nature of the Products because:

a. Defendants were in a superior position to know the true quality, safety and efficacy of the Defendants' Pelvic Mesh Products;

b. Defendants knowingly made false claims about the safety and quality of the Defendants' Pelvic Mesh Products in the documents and marketing materials Defendants provided to the FDA, physicians, and the general public; and

c. Defendants fraudulently and affirmatively concealed the defective nature of the Defendants' Pelvic Mesh Products from Plaintiffs.

112. The facts concealed and/or not disclosed by Defendants to Plaintiffs were material facts that a reasonable person would have considered to be important in deciding whether or not to purchase and/or use the Defendants' Pelvic Mesh Products.

113. At all times herein mentioned, Defendants, and each of them, willfully, intentionally, and maliciously concealed facts as set forth above from Plaintiffs and their physicians, and therefore, Plaintiffs, with the intent to defraud as herein alleged.

114. Defendants intentionally concealed and/or failed to disclose the true defective nature of the Products so that Plaintiffs would request and purchase the Defendants' Pelvic Mesh Products, and that her healthcare providers would dispense, prescribe, and recommend the Defendants' Pelvic Mesh Products, and Plaintiffs justifiably acted or relied upon, to her detriment, the concealed and/or non-disclosed facts as evidenced by her purchase of the Defendants' Pelvic Mesh Products.

115. At all times herein mentioned, neither Plaintiffs nor their physicians were aware of the facts set forth above, and had they been aware of said facts, they would not have acted as they did, that is, would not reasonably relied upon said representations of safety and efficacy and utilized the AMS' pelvic mesh products for treatment of stress urinary incontinence and pelvic organ prolapse. Defendants' failure to disclose this information was a substantial factor in Plaintiffs' physicians selecting Defendants pelvic mesh products and procedures for treatment of stress urinary incontinence and pelvic organ prolapse. This failure to disclose also resulted in the provision of incorrect and incomplete information to the plaintiff-patients.

116. As a direct and proximate result of this conduct, Plaintiffs were injured.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT IV
NEGLIGENT MISREPRESENTATION

117. Plaintiffs incorporate by reference all prior and subsequent paragraphs of this Complaint as if fully set forth herein and further allege as follows.

118. Defendants had a duty to accurately and truthfully represent to the medical and healthcare community, Plaintiffs, and the public, that the Pelvic Mesh Products had not been adequately tested and found to be safe and effective for the treatment of incontinence and prolapse. The representations made by Defendants, in fact, were false.

119. Defendants failed to exercise ordinary care in the representations concerning the Pelvic Mesh Products while they were involved in their manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce, because Defendants negligently misrepresented the Pelvic Mesh Products' high risk of unreasonable, dangerous, adverse side effects.

120. Defendants breached their duty in representing that the Defendants' Pelvic Mesh Products have no serious side effects different from older generations of similar products and/or procedures to Plaintiffs, Plaintiffs' physicians, and the medical and healthcare community.

121. As a foreseeable, direct and proximate result of the negligent misrepresentation of Defendants as set forth herein, Defendants knew, and had reason to know, that the Pelvic Mesh Products had been insufficiently tested, or had not been tested at all, and that they lacked adequate and accurate warnings, and that they created a high risk, and/or higher than acceptable

risk, and/or higher than reported and represented risk, of adverse side effects, including, erosion, pain and suffering, surgery to remove the products, and other severe and personal injuries, which are permanent and lasting in nature.

122. As a direct and proximate result of the Defendants' conduct, Plaintiffs have been injured, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, economic damages, and death.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT V
LOSS OF CONSORTIUM

123. Plaintiffs incorporate by reference all prior and subsequent paragraphs of this Complaint as if fully set forth herein and further allege as follows.

124. As a direct and proximate result of the above-described injuries sustained by Plaintiff, Plaintiff's spouse suffered a loss of spousal consortium, companionship, society, affection, services and support.

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and requests compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT VI
PUNITIVE DAMAGES

125. Plaintiffs incorporate by reference all prior and subsequent paragraphs of this Complaint as if fully set forth herein and further allege as follows.

126. Defendants sold their Products to the Healthcare providers of Plaintiff and other healthcare providers in the state of implantation and throughout the United States without doing adequate testing to ensure that the Products were reasonably safe for implantation in the female pelvic area.

127. Defendants sold the Products to Plaintiff's health care providers and other health care providers in the state of implantation and throughout the United States in spite of their knowledge that the Products can shrink, disintegrate and/or degrade inside the body, and cause the other problems heretofore set forth in this Complaint, thereby causing severe and debilitating injuries suffered by Plaintiff and numerous other women.

128. Defendants ignored reports from patients and health care providers throughout the United States and elsewhere of the Products' failures to perform as intended, which lead to the severe and debilitating injuries suffered by Plaintiff and numerous other women. Rather than doing adequate testing to determine the cause of these injuries, or to rule out the Products' designs or the processes by which the Products are manufactured as the cause of these injuries, Defendants chose instead to continue to market and sell the Products as safe and effective.

129. Defendants knew the Products were unreasonably dangerous in light of their risks of failure, pain and suffering, loss of life's enjoyment, remedial surgeries and treatments in an effort to cure the conditions proximately related to the use of the Products, as well as other severe and personal injuries which were permanent and lasting in nature.

130. Defendants withheld material information from the medical community and the public in general, including Plaintiff, regarding the safety and efficacy of the Products.

131. Defendants knew and recklessly disregarded the fact that the Products caused debilitating and potentially life altering complications with greater frequency than feasible

alternative methods and/or products used to treat pelvic organ prolapse and stress urinary incontinence.

132. Defendants misstated and misrepresented data and continue to misrepresent data so as to minimize the perceived risk of injuries caused by the Products.

133. Notwithstanding the foregoing, Defendants continue to aggressively market the Products to consumers, without disclosing the true risks associated with the Products.

134. Defendants knew of the Products' defective and unreasonably dangerous nature, but continued to manufacture, market, distribute, and sell the Products so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiff.

135. Defendants continue to conceal and/or fail to disclose to the public, Plaintiff, the serious complications associated with the use of the Products to ensure continued and increased sales of the Products.

136. Defendants' conduct as described herein shows willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care which raises the presumption of conscious indifference to consequences, thereby justifying an award of punitive damages.

IV. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Defendants, and each of them, individually, jointly, and severally and request compensatory damages, together with interest, cost of suit, attorneys' fees, and all such other relief as the Court deems just and proper as well as:

A. All general, statutory, and compensatory damages, in excess of the amount required for federal diversity jurisdiction and in an amount to fully compensate Plaintiffs for all injuries and damages, both past and present;

B. All special and economic damages, in excess of the amount required for federal diversity jurisdiction and in an amount to fully compensate Plaintiffs for all of their injuries and damages, pain and suffering;

C. Attorneys' fees, expenses, and costs of this action;

D. Double or triple damages as allowed by law;

E. Punitive and/or exemplary damages;

F. Pre-judgment and post-judgment interest in the maximum amount allowed by land; and

G. Such further relief as this Court deems necessary, just, and proper.

V. DEMAND FOR JURY TRIAL

Plaintiffs demand a trial by jury on all issues so triable.

Dated: March 28, 2022

Respectfully submitted,

/s/ Wendy R. Fleishman

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Attorneys for Plaintiff

CERTIFICATE OF SERVICE

I hereby certify that on March 28, 2022, I electronically filed the forgoing, with the Clerk of Court using the CM/ECF system, which will send notification of such filing to all counsel of record.

/s/ Wendy R. Fleishman
Wendy R. Fleishman